

REMARKS/ARGUMENTS

REJECTION UNDER 35 USC §102

Claims 1-7 and 10-14 are rejected as being anticipated by U.S. Patent no. 6,599,891 to North et al. (North). The Examiner alleges that North teaches a method for treating macular edema using light with a wavelength of between 550 and 695 nanometers with a preferred dosage between 1 and 50 J/cm². However, Applicant's disagree.

Specifically, claim 1, from which claims 2-7 and 10-14 depend, recites exposing the patient to light having a wavelength between 630 – 1000 nm and intensity between 10 – 90 mW/cm² for 1 – 3 minutes, and observing restoration or protection of visual function. In contrast, North teaches administering an effective amount of a photosensitizer to the patient and irradiating the patient with light having a wavelength absorbed by the photosensitizer. Thus, Applicants respectfully submit that North does not teach every element of the present claims. In fact, North teaches away from the present claims, by teaching PhotoDynamic Therapy (PDT) to treat macular edema.

As seen in the attached Exhibit A, PDT was developed in the 1970's as a ternary treatment for cancer involving three key components: a photosensitizer, light and tissue oxygen. Critical to the success of PDT, and to the teachings of North, is the use of the photosensitizer, a chemical compound that can be excited by light of a specific wavelength.

In short, North teaches the use of PDT to kill injured cells using a photactivatable chemical administered to the patient in combination with light. In contrast, the present claims recite healing injured cells using only far-red to near-infrared light.

Therefore, Applicants respectfully submit that North does not anticipate every element of claims 1-7 and 10-14, and these claims are now in condition for allowance. Withdrawal of the rejection is respectfully requested.

REJECTION UNDER 35 USC 103.

Claims 8-9 are rejected under as being unpatentable over North and further in view of Rosner et al. "Dose and Temporal Parameters in Delaying Injured Optic Nerve Degeneration by Low-energy Laser Irradiation," *Laser Surgery Med.* 13:61 1-617, 1993 (Rosner).

North is discussed above. In short, North teaches administering to a patient an effective amount of a photosensitizer compound and irradiating said compound with light to kill injured cells. The Examiner alleges it would have been obvious to use the methods of North to treat eye injury or damage according to the present claims. However, nothing in North teaches or suggests that removing the photosensitizer compound would be feasible, let alone successful. In fact, North teaches away from such a modification, as the key to PDT is the use of the photosensitizer compound. Applicants respectfully

submit that one of skill in the art would not be motivated to modify the teachings of North to achieve the present claims. Given the attached description of PDT, this is especially true.

Regarding Rosner, the Examiner alleges that Rosner teaches the use of low energy laser radiation once a day for 14 days to delay the degeneration of injured optic nerves. However, with North removed as a reference, Applicants do not believe that the Examiner's cited combination teaches the present invention. However, Applicants also point out that even if North were prior art, Rosner does not combine to teach the present invention because Rosner states explicitly that "non-coherent infrared light was ineffective or adversely affected the injured nerves..." [from the Abstract]. The authors conclude:

1. Coherent 632.8 nm He-Ne laser stimulation at an energy density of 40-132 J/cm² delays post-traumatic degeneration of the injured optic nerve.
2. Non-coherent 904 + 20 nm LED stimulation at an energy density 17-25 J/cm² was ineffective or adversely affected the injured nerves.

Applicants claim and describe protection at wavelengths between [claim 1] 630 –1000 nm and [claim 3] 670 – 900 nm. Applicants also claim and describe optimal energy densities of [claim 5] 2 – 10 J/cm² or [claim 4] 0.5 – 20 J/cm². Rosner teaches that Applicants' method of NIR-LED would not work because the light is (1) noncoherent and (2) the energy density is too low. According to these authors, one must use coherent laser light and the energy density would need to be at least 40 J/cm².

In conclusion, Rosner strengthens Applicants' argument that their claims are not obvious because Rosner directly states that NIR LED treatment at an energy density between 17-25 J/cm² is ineffective or harmful.

CONCLUSION

No extension of time is believed due, but should any additional extension be due, in this or any subsequent response, please consider this to be a petition for the appropriate extension and a request to charge the extension fee to Deposit Account No. 17-0055. No additional fees are believed due; however, if any fees are due, in this or any subsequent response, please charge Deposit Account 17-0055.

Respectfully submitted,

Janis T. Eells, et al.

By: *Ann E. Rabe*
Ann E. Rabe, Reg. No. 56,697
Quarles & Brady LLP
Attorney for Applicant
411 East Wisconsin Avenue
Milwaukee, WI 53202-4497
414/277-5613